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Feasibility and outcomes of Fibreoptic Endoscopic Evaluation of Swallowing **following** prophylactic swallowing rehabilitation in head and neck cancer

Short running title

Feasibility of FEES for prophylactic swallowing rehabilitation in head and neck cancer

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Abstract

Objectives: Investigate the feasibility and outcomes of fiberoptic endoscopic evaluation of swallowing (FEES) **following a programme of** prophylactic swallowing exercises in head and neck cancer (HNC) patients treated with radiotherapy.

Design: Prospective, single cohort, feasibility study

Setting: Three head and neck cancer centres in Scotland

Participants: Pre-radiotherapy HNC patients who consented to participate in a prophylactic swallowing intervention.

Outcome measures: FEES recruitment and retention rates, assessment acceptability and compliance, qualitative process evaluation

Results: Higher rates of recruitment and retention were achieved in centres where FEES equipment was available on site. Travel and anticipated discomfort were barriers to recruitment. Data completion was high for all rating scales, with good reliability. Following radiotherapy, swallowing safety significantly deteriorated for liquid boluses ($p=0.005-0.03$); pharyngeal residue increased for liquid and semi-solid boluses. Pharyngo-laryngeal oedema was present pre-treatment and significantly increased post-radiotherapy ($p=0.001$). Patients generally reported positive experience of FEES for their own learning and establishing a baseline.

Conclusions: FEES is an acceptable method of assessing patients for a prophylactic swallowing intervention and offers some additional information missing from VF. Barriers have been identified and should be taken into account in order to maximise recruitment for future trials.

Key words

Head and neck cancer, radiotherapy, dysphagia, rehabilitation, intervention, Fiberoptic Endoscopic Evaluation of Swallowing, feasibility

Key points

- FEES offers a unique perspective in evaluating swallowing rehabilitation in post-radiotherapy HNC patients
- Consideration needs to be given to treatment pathways and equipment access when using FEES for research purposes, in this group of patients
- The described swallowing assessment protocol was feasible to conduct and rate

Background

Dysphagia as an acute and long-term side-effect of non-surgical treatment for head and neck cancer (HNC) is a commonly reported phenomenon. Chemoradiotherapy can result in fibrotic, atrophic, insensate, oedematous tissues, affecting movement and coordination necessary for safe and efficient swallowing. (1-4). This is a serious medical concern associated with malnutrition and possibly pneumonia, as well as having significant impact on patients' quality of life(5).

There is an increasing body of evidence investigating swallowing exercises introduced before chemoradiotherapy, in order to maintain muscle function and reduce the potential for disuse atrophy. Evidence for the effectiveness of this complex intervention is conflicting. A Cochrane review (6) precluded a study comparison, due to a range of outcome measures being reported. Swallowing safety and efficiency can only be reliably measured using instrumental assessment, including videofluoroscopy (VF) and Fiberoptic Endoscopic Evaluation of Swallowing (FEES). VF has been employed in prophylactic exercise research (7-10), reporting on rates of penetration-aspiration, oropharyngeal efficiency and residue. VF for research purposes presents a number of challenges such as cost, access, radiation exposure, as well as the addition of radio-opaque substances, altering bolus consistency.

FEES can also be used to record penetration-aspiration events and residue but has not yet been used as a tool to measure the effects of prophylactic exercises. Furthermore, FEES allows assessment of laryngopharyngeal oedema severity, so far unreported in prophylactic exercise studies. Aspects of FEES feasibility including acceptability, assessment and protocol completion, outcome measurement and barriers to completion are currently unknown. The aim of this study was to investigate the feasibility and outcomes of using FEES to evaluate our prophylactic swallowing intervention programme in HNC (11).

Materials and methods

This is a multi-centre, mixed methods, cohort study to explore feasibility and acceptability of FEES in a HNC prophylactic swallowing intervention package (SIP).

Patients

The SIP protocol has been published (11), with FEES only being conducted in the experimental group to test for feasibility. Consented patients were approached for FEES (SIP-FEES) as part of a panel of outcome measures; participation in SIP-FEES was not mandatory for inclusion in SIP. The study took place across three sites. Site 1 had FEES equipment in the same hospital as the radiotherapy treatment. Sites 2 and 3 had FEES equipment in a separate hospital, away from the radiotherapy centre, requiring a separate visit to attend FEES assessment. After an initial approach by a Speech and Language Therapist (SLT) or Clinical Nurse Specialist (CNS), research nurses recruited and consented patients to the study.

Assessment

FEES was conducted using a nasendoscope attached to a camera and digital recording system. Assessments were carried out by specialist SLTs. Test boluses were given in the following order: 5 mls, 10mls and 20mls of milk in a cup, teaspoon of custard, teaspoon of mashed banana and ¼ of

biscuit. FEES took place pre-radiotherapy and at 3 months post-radiotherapy. To assess rater reliability, examinations were rated by an independent SLT blinded to details and 10% were re-rated by a second SLT.

Feasibility and acceptability outcomes

1. Acceptability was measured by the proportion of patients approached and consented for FEES. Retention rates and reasons for drop out were documented.
2. Feasibility and compliance were measured by assessing FEES protocol completion. Time taken to complete and rate the protocol was recorded. Number of incomplete bolus tests and poor quality images were noted.
3. A selection of rating scales was chosen to identify appropriate outcome tools. Acceptability was monitored by data completion. Three rating scales were selected to measure safety, residue and oedema: Penetration Aspiration Scale (PAS) (12) , an 8-point scale describing laryngeal penetration and aspiration and sensory response; Yale Pharyngeal Residue Severity Rating Scale (YPRS) (13), a 5-point scale used to rate severity of pharyngeal residue in the valleculae and pyriform sinuses; Patterson's Oedema Scale (POS) (14), a 4-point rating scale of 11 structures and two spaces in the laryngopharynx.

Data analysis

Paired t-tests and Wilcoxon signed rank test for paired parametric and non-parametric data respectively and Chi square test was used for categorical data.

Qualitative sub-study

Patients were purposely sampled for a range of age, gender, cancer stage, and treatment regime, and were invited for interview from 6 weeks post-radiotherapy. Semi-structured interviews lasted around an hour and were recorded, transcribed, and coded using NVIVO 11 software. Initial thematic codes were developed from the data by two researchers. Codes were reviewed and condensed by one of the original researchers, plus one other.

SLTs, CNSs and research nurses were also invited for interview regarding SIP. Interviews were recorded, transcribed and analysed using Normalisation Process Theory (15, 16).

Ethical approval

Ethical approval was granted by the East of Scotland Research Ethics Service (REC: 15/ES/0106; NRS R&D: NRS15/ON703) Informed written patient consent was gained.

Results

Thirty-two patients consented to participate in SIP, with 66% consenting to SIP-FEES (see Table 1). There were no significant differences for age, gender, tumour size, site or treatment type between those that consented for SIP-FEES and those that did not.

Recruitment and retention

At site 1 all patients who consented to SIP also agreed to SIP-FEES, with one patient being unable to complete the baseline assessment due to illness. At sites 2 and 3, 55% of patients declined SIP-FEES. Twenty-one pre-treatment FEES were available for analysis (see Table 2). Reasons given for declining SIP-FEES at these sites were due to potential discomfort of the examination and travel involved in attending the appointment.

Following treatment, one patient at each site dropped out of SIP. All available patients at site 1 had a three month post-treatment FEES. Two patients dropped out at site 3 for SIP-FEES, leaving 17 post-treatment FEES available for analysis. Retention for SIP-FEES was 81%. Reasons for drop out post-treatment were travel-related.

Protocol compliance and acceptability

The SIP-FEES protocol took on average 20 minutes to complete and 15-20 minutes to rate. The majority of test boluses were administered. One patient refused custard and five solid boluses were not given due to patient refusal or swallow safety concerns. Only one bolus was re-administered due to inadequate picture from residue. The PAS, YPRS and POS ratings were completed for all boluses.

Rating scales

There was 77-94% agreement between raters to +/- 1 point across all scales.

Penetration Aspiration Scale

No aspiration was observed pre-treatment. Deterioration in scores from pre- to post-treatment were observed as anticipated. There was greater deterioration for fluid and semi-solid boluses than soft-solid and solid textures, with the fluid boluses being statistically significant (see Table 3). Higher aspiration incidence occurred on fluids (n=5) than solid boluses (n=1).

Yale Residue Scale

Pre-radiotherapy residue ranged from none-moderate, with no rating of severe. Deterioration in scores from pre- to post-radiotherapy were observed (see Table 4), although none were statistically significant (Chi square $p>0.05$). Where gross oedema obliterated the valleculae or pyriform sinuses, residue was rated according to the relationship with geographical boundaries (i.e. aryepiglottic folds) rather than residue volume. In some instances, residue was identified outside of these spaces and could not be rated.

Patterson's oedema scale

Pre-radiotherapy laryngopharyngeal oedema ranged from none-moderate, except for two cases of severe vocal fold oedema. Oedema increased from pre- to post-radiotherapy and was statistically

significant (see Table 5). The full range of the scale was used post-radiotherapy, with all patients having at least mild oedema present in either the larynx or pharynx.

Qualitative Interviews

Seventeen patients were interviewed, 8 of whom had consented to SIP-FEES. Six SLTs, four CNSs and five research nurses were interviewed for the main study. Analysis of data relating to FEES identified three main themes; resources, FEES-specific issues and processes and logistics (see Table 6). There were positive and negative comments in clinician and patient interviews for the domains of FEES-specific issues and process logistics.

FEES was less problematic when equipment was located on-site, not just for patient ease but because staff could 'catch' patients between appointments. Not all SLTs were qualified to perform endoscopy, limiting capacity.

Most patients found FEES positive, and indeed helpful in seeing and understanding swallowing functioning and recording a baseline. The degree of patient comfort for scope placement varied. Implementing FEES into the research and clinical care pathway took detailed planning and organisation. Recruitment was enhanced by adapting and negotiating the pathway to reduce the number of appointments and travel.

Discussion

This is the first study to report on the feasibility and acceptability of FEES in prophylactic swallowing intervention research. Results indicate that future recruitment may be enhanced by addressing barriers identified by this study. Recruitment varied across sites and was highest where FEES equipment was available in the same site, allowing for greater flexibility to fit around a complex clinical pathway. Reasons for declining follow-up FEES were mainly due to travel rather than discomfort. Site location and transportation is a common problem for retention (17). Consideration should be given to equipment availability when selecting assessment tools and sites.

A process evaluation of recruitment and consent conversations was not conducted, however as clinicians are more knowledgeable about swallowing assessments, we hypothesise that they were more able to provide detailed FEES information. Some patients were highly motivated to have FEES, so that they could better understand swallow function and to compare how this had changed following treatment. Clinician approach and consent has increased patient participation in other studies (18), however this needs to be traded against time pressures and potential coercion within a therapeutic relationship (19). Research nurses may have benefitted from further training regarding the swallowing assessments (20).

Comparison with other studies

The protocol and rating scales were quick, with a high proportion of data completeness. Outcomes showed minimal pre-treatment airway invasion for all boluses, less than previous reports (21). There was significant deterioration in penetration-aspiration scores following radiotherapy, similar to other studies (21). Minimal change was observed for solid boluses. An increase in the incidence of residue was seen, with a trend for this to be greater for fluids and semi-solids than solids, occurring more frequently in the valleculae than pyriform sinuses. Studies have found that swallowing exercises

reduce solid bolus residue (22, 23), which may account for the pattern observed here. Residue is an important consideration, having greater impact on quality of life than aspiration (24) and should be included in a panel of outcome measures.

FEES enabled an assessment of oedema which is strongly associated with swallowing function (25). Oedema was recorded pre-radiotherapy, similar to other published findings (1), which could be due to tumour, post-biopsy swelling, smoking and or reflux. This did not appear to impact on swallowing safety, but may have influenced the presence of mild residue. There was a significant increase in oedema post-radiotherapy. Further work is needed to evaluate whether exercises reduce internal oedema, which is thought to be a precursor to fibrosis.

Strengths

Few studies have reported on the utility of FEES in HNC research. This was a pragmatic study, allowing for comparison of FEES acceptability across different geographical locations and recruitment strategies. Small subject numbers were commensurate with feasibility work, but identified important issues for successful recruitment and retention.

Clinical applicability

FEES is acceptable and, in some cases, desirable for patients wishing to better understand their swallowing. This protocol and rating scales were quick to perform and therefore may be adaptable to the clinical situation, especially when repeated assessment is required as part of regular follow-up.

Conclusions

FEES is a flexible, convenient and valid alternative to VF for instrumental swallow evaluation. FEES is a logistically complex undertaking, and inclusion in future research protocols would need to be carefully considered in terms of equipment, staff availability and assessment rating protocols.

Conflict of Interest

None declared

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Table legends

Table 1 Patient characteristics for patients recruited to SIP and patients participating in SIP-FEES

Table 2 Patient numbers for pre-radiotherapy recruitment and retention at 3 months to SIP and SIP-FEES across 3 sites

Table 3 Pre- to post radiotherapy comparison of PAS and summary of penetration / aspiration events

Table 4 Pre- to post radiotherapy (at 3 months) comparison of YPRS for each test bolus on FEES

Table 5 Summation of POS pre- and post-radiotherapy and comparison over time. A higher score indicates greater oedema severity.

Table 6 Summary of qualitative interviews with clinicians and staff (SLT=speech & language therapist, CNS=clinical nurse specialist, RN=research nurse)

Table 1 Patient characteristics for patients recruited to SIP and patients participating in SIP-FEES

	SIP total (n=32)	SIP-FEES (n=21)
Gender N(%)		
Male	29	20
Female	3	1
Age		
Mean (SD)	61.8 (9.1)	58.8 (8.0)
Tumour site N(%)		
Oral	5	1
Oropharynx	17	13
Hypopharynx	1	1
Larynx	4	3
Nasopharynx	2	1
Unknown	3	2
Tumour stage		
T0	3	2
T1	11	7
T2	6	5
T3	1	1
T4	11	6
N stage		
N0	6	3
N1	3	1
N2	22	16
N3	1	1
Treatment N(%)		
Radiotherapy	8 (25%)	5 (24%)
ChemoRT	19 (59%)	13 (62%)
Surgery and (chemo)RT	5 (16%)	3 (14%)

Table 2 Patient numbers for pre-radiotherapy recruitment and retention at 3 months to SIP and SIP-FEES across 3 sites

Site	Recruitment to SIP at baseline	Pre-treatment FEES consented	Retention in SIP at 3 months	Retention in SIP-FEES at 3 months
Site 1	12	12	11	11
Site 2	14	5	13	5
Site 3	6	4	5	1
Total	32	21 (66%)	29	17 (53%)

Test bolus	Pre-to post PAS	Pre (n=21)		Post (n=17)	
5ml milk	Z= -2.2 p=0.03	None	18	None	9
		Penetration	2	Penetration	7
		Aspiration	0	Aspiration	1
		Not assessed	1		
10ml milk	Z=-2.8 p=0.005	None	19	None	7
		Penetration	1	Penetration	5
		Aspiration	0	Aspiration	5
		Not assessed	1		
20ml milk	Z=-2.8 p=0.005	None	19	None	6
		Penetration	1	Penetration	6
		Aspiration	0	Aspiration	5
		Not assessed	1		
Custard	Z=-1.9 p=0.06	None	18	None	10
		Penetration	1	Penetration	7
		Aspiration	0	Aspiration	0
		Not assessed	2		
Banana	Z=-1.0 p=0.32	None	20	None	16
		Penetration	0	Penetration	1
		Aspiration	0	Aspiration	0
		Not assessed	1		
Biscuit	Z=-1.0 p=0.32	None	16	None	14
		Penetration	1	Penetration	0
		Aspiration	0	Aspiration	1
		Not assessed	4	Not assessed	2

Table 3 Pre- to post radiotherapy comparison of PAS and summary of penetration / aspiration events

Table 4 Pre- to post radiotherapy (at 3 months) comparison of YPRS for each test bolus on FEES

	Pre (n=21)			Post (n=17)		
		Valleculae	Pyriforms		Valleculae	Pyriforms
5ml milk	Non-trace	13 (62%)	15 (70%)	Non-trace	4 (24%)	5 (30%)
	Mild	7 (33%)	5 (25%)	Mild	6 (35%)	2 (12%)
	Moderate	0	0	Moderate	6 (35%)	8 (46%)
	Severe	0	0	Severe	1 (6%)	2 (12%)
	Not assessed	1 (5%)	1 (5%)			
10ml milk	Non-trace	14 (67%)	15 (70%)	Non-trace	2 (12%)	4 (24%)
	Mild	6 (28%)	4 (20%)	Mild	9 (52%)	2 (12%)
	Moderate	0	1 (5%)	Moderate	4 (24%)	7 (40%)
	Severe	0	0	Severe	2 (12%)	4 (24%)
	Not assessed	1 (5%)	1 (5%)			
20ml milk	Non-trace	7 (33%)	14 (65%)	Non-trace	0	4 (24%)
	Mild	12 (57%)	5 (25%)	Mild	10 (58%)	3 (18%)
	Moderate	1 (5%)	1 (5%)	Moderate	4 (24%)	6 (36%)
	Severe	0	0	Severe	3 (18%)	4 (24%)
	Not assessed	1 (5%)	1 (5%)			
Custard	Non-trace	12 (57%)	14 (65%)	Non-trace	2 (12%)	9 (52%)
	Mild	7 (33%)	5 (25%)	Mild	3 (18%)	3 (18%)
	Moderate	1 (5%)	1 (5%)	Moderate	5 (30%)	5 (30%)
	Severe	0	0	Severe	7 (40%)	0
	Not assessed	1 (5%)	1 (5%)			
Banana	Non-trace	15 (70%)	22 (96%)	Non-trace	9 (52%)	17(100%)
	Mild	2 (10%)	1 (4%)	Mild	3 (18%)	0
	Moderate	3 (15%)	0	Moderate	3 (18%)	0
	Severe	0	0	Severe	2 (12%)	0
	Not assessed	1 (5%)				
Biscuit	Non-trace	11(56.5%)	14 (65%)	Non-trace	5 (29%)	12 (70%)
	Mild	3 (12.5%)	1 (5%)	Mild	2 (12%)	3 (18%)
	Moderate	5 (12.5%)	2 (10%)	Moderate	3 (18%)	0
	Severe	0	0	Severe	5 (29%)	0
	Not assessed	3 (12.5%)	4 (20%)	Not ax	2 (12%)	2 (12%)

Table 5 Summation of POS pre- and post-radiotherapy and comparison over time. A higher score indicates greater oedema severity

	Pre- radiotherapy	Post radiotherapy	Pre- to post
Laryngeal (range 0-21)	median 6; IQR 3-9; range 0-12	median 14; IQR 13-20; range 0-21	Z=-3.2 p=0.001
Pharyngeal (range 0-9)	median 1; IQR 0-3; range 0-6	median 6; IQR 6-7; range 0-9	Z=-3.4 p=0.001

Table 6 Summary of qualitative interviews with clinicians and staff (SLT=speech & language therapist, CNS=clinical nurse specialist, RN=research nurse)

Theme	Sub-theme	Examples
1) Resources		
	Finding space	<i>Occasionally we went down when they were having their chemotherapy and whilst they were hooked up to their chemotherapy infusion, we went down to the infusion suite and did it there, because it's quite a long way from here to the oncology department, but we were able to do that, because it's easy enough to do. (SLT2)</i>
	Equipment	<i>I know SLT1, they had accessed the hardware, the nasendoscopy and the FEES equipment and obviously without that it would have been - no way to do anything (CNS2)</i>
	Length of assessment	<i>The FEES itself wasn't particularly lengthy, you know, it wasn't as involved as our normal FEES appointment would usually be for us. We weren't looking at all those different parameters, it was just, okay, the protocol with the liquid and the pudding and the...so, yeah, the FEES component of it was okay but, again, you've just got the setup of the machine, the explanation to people quite often after you've done that. (SLT6)</i>
	Staffing	<i>We don't really have enough staff or space to run things like, somebody doing the intervention well, somebody scoping and swapping people over. We're just not big enough for that, really (SLT6)</i>
	Location	<i>I spoke to one patient who refused the FEES because it was at [site 3] and he'd already been to five different hospitals I think for, you know, I think they have to get their peg fitted at [another site] and then they've got two hospitals in [location] and then they're over at [site 3] and he just, kind of, I think it was just too much (RN)</i> <i>They spoke at one time about going to [site 3] to do this, and I says no. I wasn't going to do that because I got just at that time that they mentioned it, I'd been involved with four different hospitals. (Patient 1, male)</i>
2) FEES specific issues		
	Prior experience	<i>Unfortunately if they've...well, pretty much they all have been scoped and some patients are stoic and some patients less so but it does make a difference, I think, because if they've had a bad experience they will just say, there's no way you're putting that thing in my nose. (SLT3)</i>
	FEES as educational tool	<i>Yeah. So the ones that want...because not everybody wants to see it, but the ones who do want to see it, I think it does help to give them feedback in terms of understanding what it is that's wrong, especially when they lack sensation, so we're saying, oh, there's food sticking here or there's food sticking there or you haven't cleared...we often ask has</i>

		<p>everything gone, can you feel anything in your throat? And they'll say, no, everything's gone, there's nothing there and you've got lumps of banana sitting in their throat. So I think for that kind of patient, it's really useful. (SLT2)</p> <p>Oh, to have a look at the back of my throat? Oh yeah. Oh, that was really good.(Patient 2 Female)</p>
	Establishing a baseline	<p>It's easier to show them because we can catch them and say this is your swallow as it was and this is it now - so they've found that that's a very useful kind of educational tool and rehabilitation tool, you know, because patients could actually gauge their kind of recovery in that way (CNS2)</p> <p>And having a baseline record of that is useful. It's useful for me as much as anything else to know where I was at the beginning (Patient 2 female)</p>
	Level of comfort	<p>and it just felt it was sticking into the back of my throat. So I started to heave, and I was sick. So I just couldn't do it (Patient 2, male)</p> <p>So nothing horrible happens, it's just seeing how well you can cope normally with these types of food (Patient 2, female)</p>
	Scopist	<p>No, it was okay. I mean, initially, it depends who's doing it, some of the girls are very good, you wouldn't even hardly feel it. Other ones, it's like they're trying to rod a drain, you know.. (Patient 2, male)</p>
	Anxiety	<p>I felt mean not contributing to that bit but I thought you know what I can't subject myself to more anxiety than I already have had. (Patient 2 female)</p>
3) Processes and Logistics		
	Fitting in to the pathway	<p>I think one or two we've had issues because consent has come in very late and that's a real problem and then in terms getting the pack and doing the FEES I think there was one we got notification of his consent two days before he was due to start his treatment (SLT1)</p> <p>That's been going fine, again, it's just the scheduling in. But I think SLT2 and I are getting quite adaptable and, I think, we don't mind doing that on day one of treatment where we can usually catch people. It's often a long day for them so that works reasonably well. (SLT 3)</p>
	Organisation	<p>I think SLT3 was very, very good at keeping us all right and who's where and when and what we needed to do. I think she</p>

		<i>very much coordinated that for all of us, and as soon as she wasn't here there was that slight rising panic of, what do I need to do for SIP when I can't check with SLT3? In fairness to her, she had a spreadsheet with who was at what point and what they had had and agreed to in terms of FEES and not, and that sort of thing (SLT6)</i>
	Presentation of information	<i>Whereas for me because it involved a different day, another appointment, travel, you have to kind of negotiate a bit more about it. You can't just be like, right, you've seen the doctor now come into this room and have your FEES and intervention. It was much more of a negotiation which did make a difference I think. (SLT3)</i>
	Endoscopy as a routine assessment	<p><i>We understood that it's not a pleasant thing to go through, you know, but you are going to have to at the end of the day nasendoscopy are going to come very, you know, a very usual part of your regime and your follow up after this. I don't think they like it but they tolerate it. (CNS2)</i></p> <p><i>It's the only thing out of the whole lot of it I didn't like, but I'm used to it now though, because we make a joke of it now, I make a joke every time I'm in it. (Patient 2 male)</i></p>